IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Malik et al.	Examiner: Uyen T. Ho
Serial No.: 09/997,449	Art Unit: 3731
Filed: November 30, 2001	
Title: A Modified Implantable Device Surface And A Method Of Making The Same	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration Under 37 C.F.R. § 1.132

I, Dr. Pamela Kramer-Brown, declare the following:

1. I received a Ph.D. in Materials Science Engineering from U.C. Berkeley in 1998. I received an M.S. in Materials Science Engineering from U.C. Berkeley in 1992 and a B.S. in Mechanical Engineering and Materials Science Engineering from U.C. Berkeley in 1988.

2. I am currently employed by Abbott Vascular, formerly Guidant Corporation, as an Advisor and Technical Manager on material research and development.

3. I was a Principal Engineer and Senior R&D Engineer at Guidant Corporation from 1998 to 2005. My duties included research and development of stent materials. I was responsible for developing new materials, implementing key technology development methods, and contributing to the creation and revision of ASTM standards critical to the medical device industry.

4. I was a Graduate Researcher at E.O. Lawrence Berkeley National Laboratory from 1989 to 1998. My duties included research on aluminum alloys with discrete surface patterns and Sn/Pb materials containing low gold concentrations.

5. I was a Scientist Associate at Lockheed Missiles and Space Co. in 1989. I performed research on refractory metal alloys, as well as other projects related to material science.

6. My professional affiliations include ASM International, ASTM, ISMRM, MRS, and TMS.

7. I have read and understand application serial number 09/997,449 ('449), owned by Abbott Vascular.

8. I submit that from reading the Davidson patent, US Patent No. 5,415,704, I easily recognize that the teachings of the specification.

9. I submit that an alloy having hardness exceeding 60 Rockwell C as taught in Davidson can not be used in stents as in '449 because such hardness does not provide adequate flexibility in stents (Col. 9, line 44-48).

10. I submit that the depth of hardness that Davidson refers to (100 microns or deeper as in tables) roughly matches or exceeds the thickness of the existing stent struts (Col. 9, lines 37-38). Having this hardness throughout the product as taught in Davidson makes the product very stiff and, it is known in the art that the harder something is, the less elongation it has, and for a balloon expandable stent it would very likely crack on expansion.

11. I also submit that Davidson teaches a method of hardening via precipitation hardening, whether with oxides, nitrides, or carbides (Col. 5, lines 54 to Col 6, lines 12). For current stents, these precipitates are undesirable from a strength perspective. Precipitates may act as crack initiation sites in high strain areas via 'fallout' (being on the stent surface, exposed during normal polishing of the stent, then falls out when the stent is expanded leaving a little hole or by cracking under the applied strain and thus having a crack at or within the surface of the stent).

12. I further declare that all statements made herein of my own knowledge are true and that all statements made upon information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title

18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Executed on _____ _____

Dr. Pamela Kramer-Brown